UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES ONLY TO: **WAVE THREE TVT, TVT-O AND TVT-S CASES LISTED ON EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF ANNE WILSON, MBA[1]

Defendants Ethicon, Inc., Ethicon LLC, and Johnson & Johnson (collectively, "Ethicon") submit this memorandum in support of their motion to exclude the opinions and testimony of Plaintiffs' designated expert in the field of documentation of compliance with risk management standards, Anne Wilson. Ms. Wilson issued separate reports for TVT, TVT-O, and TVT-S cases. Ms. Wilson's testimony should be excluded for the following reasons.

PRELIMINARY STATEMENT

This brief closely tracks Ethicon's memorandum in support of its Motion to Exclude Ms. Wilson from the Wave 1 cases. On August 25, 2016, the Court entered a Memorandum Opinion and Order [Doc. 2647] regarding the Wave 1 motion. In that Order the Court elected not to address the pure-*Daubert* issues raised in the earlier motion, "find[ing] it unnecessary to address alternate challenges to [Ms. Wilson's] reliability or qualifications" due to the fact that the Court "excluded, reserved ruling on, or otherwise addressed the admissibility of Ms. Wilson's testimony on the grounds explained below." *Id.* at 6. The Court then went on to address several "[r]ecurring issues," which dealt largely with relevancy related arguments. *See id.* at 6-10.

[1] Ex. A is a list of the cases to which the motion to exclude Anne Wilson applies. All exhibits referenced herein are attached to the motion.

Ethicon respectfully submits that in the light of the reserved rulings on the recurring issues, taking up the pure-*Daubert* arguments in this brief is the proper course here. Doing so may lead to a conclusive disposition regarding the admissibility (or lack thereof) of Ms. Wilson's testimony. For example, the Court previously reserved ruling on whether Ms. Wilson would be allowed to offer opinion testimony that Ethicon allegedly failed to comply with the regulatory standards of foreign nations, noting that the Court was refraining from issuing a blanket exclusion because product liability law varies from state to state. However, the issue of whether Ms. Wilson applied her methodology reliable (*see* § I *infra*) is a question of federal evidentiary law that is the same for all jurisdictions. Rulings on this and the other pure-*Daubert* issues at this stage of the litigation could resolve such reliability and qualifications issues for the entire universe of cases presently pending before this Court.

INTRODUCTION

Anne Wilson is a biomedical engineer and quality assurance consultant holding certifications as a Quality Auditor and Quality Engineer. Plaintiffs designated Ms. Wilson to offer opinions (a) that Ethicon's quality management systems for the design and development of TVT, TVT-O, and TVT-S do not comply with industry standards, (b) that Ethicon improperly performed its risk analyses for these three products, (c) that Ethicon has not properly performed risk management during the lifecycle of these products, and (d) that, in particular, Ethicon failed to routinely update its risk analyses. *See generally* Ex. B, Wilson TVT Report; Ex. C, Wilson TVT-O Report; Ex. D, Wilson TVT-S Report.

The Court should exclude Ms. Wilson's opinions under *Daubert* because (a) she fails to perform the analysis required in her typical professional auditing practice, (b) she applies European regulatory standards as the bases for her opinions in all three reports, (c) she fails to consider critical

documents mandated by the standards on which she relies, (d) she misapplies the standards on which she relies, and (e) she also offers medical opinions and opinions about Instructions for Use warnings which she is manifestly unqualified to give.

The bottom line with this witness is that her testimony is unreliable, irrelevant, and at times wholly outside the scope of her qualifications. It is also an awkward violation of this Court's ruling that no regulatory testimony will be permitted. *See Wilkerson v. Boston Sci. Corp.*, 2015 U.S. Dist. LEXIS 58671, at *82-84 (S.D. W. Va. May 5, 2015). For each of these independent reasons, the Court should preclude Ms. Wilson's opinion testimony.

STANDARD FOR ADMISSIBILITY OF EXPERT OPINION TESTIMONY

Ethicon incorporates by reference the standard for *Daubert* motions as articulated in *Edwards v. Ethicon, Inc.*, 2014 U.S. Dist. LEXIS 92316, at *3-8 (S.D.W. Va. July 8, 2014).

ARGUMENT

I. Ms. Wilson Did Not Follow the Standards of Her Auditing Profession

Ms. Wilson states that her assignment in this matter was "to address the design control and risk management processes of Ethicon" associated with the manufacture of TVT, TVT-O, and TVT-S. Ex. B, TVT Report at 2; Ex. C, TVT-O Report at 2; Ex. D, TVT-S Report at 2. What Ms. Wilson did to "address" the design control and risk management processes is a mystery.

Within the field of quality systems, design control process, and risk management, there exists a valid methodology to assess whether a medical device manufacturer is complying with the applicable standards. The method is to conduct an audit.[2] Audits are performed using specified standards for reviewing the quality systems files of the device manufacturer. Ex. E, Wilson 9/17/15 Dep. Tr. 39:14-39:20. That is what the European authorities did when they audited the development of TVT in Sweden. *See* pp. 4, 20, *infra.*

[2] Alternatively, a thorough due diligence review could have been conducted.

Ms. Wilson was not hired to do an audit here and did not do one. Though she is certified to conduct such audits, that is not what she did here. Ex. E, Wilson 9/17/15 Dep. Tr. at 39:1-40:3. "So they're [i.e., the expert report "methodology" she used in this case and a design control audit] not at all the same." *Id.* at 39:14-39:20. Ms. Wilson cavalierly admitted that the "skills" she used for her expert report are not the skills that she uses in her audits but rather are "expert report skills." *Id.* at 41:12-41:15.

In addition, in the ordinary course of her profession, Ms. Wilson also uses and relies on FDA guidance documents "all the time." Ex. F, Wilson 3/22/16 Dep. Tr. 56:1-57:8. In contrast, Ms. Wilson was told to ignore FDA guidelines here. Ex. E, Wilson 9/17/15 Dep. Tr. 59:3-59:9.

She was unable to identify any particular methodology that she employed to arrive at her opinions. Ms. Wilson admitted that there are no published standards that govern the type of review that she performed in this case. *Id.* at 56:6-56:14. "I'm not aware, again, of any standard that says how to prepare an expert report for a medical device company." *Id.* at 56:23-57:2. When asked directly what methodology she employed when arriving at her opinions, she stated:

> I looked at many, many, many, many, many documents and chose those that best related to the topics of risk management, [de]sign control.
>
> And then I took those documents and reviewed them again, and started writing. Did an outline. And I kept refining and refining, and came up with my report.

Id. at 38:13-38:24.

Moreover, Ms. Wilson's opinions derived from her undefined methodology are directly contrary to the findings of independent auditors who applied the generally acceptable method for auditing such records. When true auditors applied the requisite methodology, they concluded that all requirements were fulfilled. Ex. G, EC Certificate DGM-036; Ex. H, Certificate TÜV Q1Z 00 07 39858 001; Ex. I, TÜV Audit Brief Report Order no. 70038068; Ex. J, TÜV Audit Brief Report Order no. 70063863.

In sum, Ms. Wilson works in a field that normally applies very specific U.S. standards and has a very specific procedure for how a quality systems file should be reviewed, but Ms. Wilson did not apply these standards and procedures to her work in this case. Instead, she allegedly employed a different set of "skills" – which apparently include nothing more than reading selected documents provided to her – to arrive at her litigation opinion.

This is precisely the type of unreliable methodology that *Daubert* and its progeny are aimed at preventing. "The Supreme Court has said that '[t]he objective of [the *Daubert* gatekeeping] requirement . . . is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *Mathison v. Boston Sci. Corp.*, 2015 U.S. Dist. LEXIS 59047, at *33 (S.D.W.V. May 6, 2015) (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999)). As this Court has made clear, when the "deposition testimony plainly reveals that [the designated expert] employed less intellectual rigor in forming this opinion as an expert witness than [s]he employs . . . in h[er] field," that expert's testimony is inadmissible and should be excluded. *Id.*

II. Ms. Wilson's Opinions Are Based on European Regulatory Standards that Did Not Apply to the Design of TVT

Ms. Wilson opines that Ethicon failed to meet the "industry standards" for design control process and risk management. Ex. B, TVT Report at 3-4; Ex. C. TVT-O Report at 3-4; Ex. C, TVT-S Report at 3. In support of this opinion, Ms. Wilson cites to six documents as constituting the "industry standard" -- MIL-Q-9858A, ISO 9001, EN 1441, EN 46001, ISO 13485, and ISO 14971. Contrary to Ms. Wilson's statements, these documents are not "industry standards," but rather are the regulatory standards, most of which are applicable in the European Union, not the U.S. Ex. E, Wilson 9/17/16 Dep. Tr. 96:22-102:24. Moreover, these European regulatory

standards to which she cites did not go into effect until after 1995 (i.e., after the TVT design process was complete). In other words, she chooses the wrong standards and improperly applies even those standards retrospectively.

At the time TVT was designed, there were no regulatory standards in Sweden that required regarding design controls and risk management processes. Ex. K, Duncan 10/6/15 Dep. Tr. 330:13-331:22. TVT was designed and developed by Medscand in Sweden prior to 1995. In fact, by 1995, Medscand was already manufacturing the prototype device, had applied for the patent, and had begun clinical trials. Ex. L, Arnaud 7/20/2013 Dep. Tr. 454:24-457:19. By February 1997 Ethicon had received its license from Medscand to market the final TVT product worldwide. *Id*. at 471:10-472:4. That same year Ethicon began marketing TVT in Europe. Ex. M, Arnaud 9/25/2013 Dep. Tr. 906:12-906:15. Ms. Wilson even acknowledges that the design of TVT was completed in Sweden by 1995. Ex. B, TVT Report at 4.

None of the "industry standards" cited by Ms. Wilson apply to the design of TVT:

A. MIL-Q-9858A is a U.S. military standard and is irrelevant.

First, Ms. Wilson says MIL-Q-9858A, and later ISO 9001, are industry standards that governed "QMS [Quality Management Systems] and ***associated risk management practices*** for medical devices predat[ing] the initial design of the TVT-R which occurred in 1995." Ex. B, TVT Report at 4. MIL-Q-9858A was a military specification concerning quality management of military contracts dating back to the 1950s. Ex. N, MIL-Q-9858A. These U.S. military specifications did not apply to Medscand, the Swedish company that designed TVT. Moreover, it is not clear why Ms. Wilson discusses these specifications because they say nothing at all about the design controls, risk analysis, risk assessment, and risk management that are the subjects of her reports.

B. EN 46001 and ISO 9001 are EU regulatory standards and do not concern risk assessment or management

Next, Ms. Wilson relies on EN 46001 together with ISO 9001. Ex. B, TVT Report at 4-5. EN 46001 is a European regulatory standard developed for the "application of EN ISO 9001" to the manufacture of a medical device. Ex. O, EN 46001:1996 at 1; Ex. P, ISO 9001:1994. Neither of them addresses the subjects of design risk analysis and ongoing risk assessment and risk management throughout the life of the devices that is the focus of Ms. Wilson's reports.

C. ISO 13485 was not adopted as an EU regulation until 2003

Ms. Wilson then cites ISO 13485 as "defin[ing] the requirements for proper risk analysis in the medical device industry since 1996." Ex. B, TVT Report at 5; Ex. Q, ISO 13485:1996. The FDA has never recognized ISO 13485 as a Consensus Standard. Ex. R, Guidance for Industry and Staff: Recognition and Use of Consensus Standards. The 1996 version of ISO 13485 was never adopted even in Europe. Ex. K, Duncan 10/6/15 Dep. Tr. 329:5-330:12.

At her deposition Ms. Wilson produced her own analysis of whether and when standards were implemented in which she acknowledges that she does not know of any date for implementation of ISO 13485:1996. Ex. F, Wilson 3/22/16 Dep. Tr. 13:5-14:17; Ex. S, Wilson Depo. Ex. 11. Ms. Wilson also acknowledges that ISO 13485:1996 was not even first released until December 26, 1996, more than a year after all design work on TVT had been completed. *Id*. Moreover, far from "defining the requirements for risk analysis," ISO 13485 makes only two references to risks:

> (1) Section 4.4.1 states "[t]hroughout the design process, the supplier shall evaluate the need for risk analysis and maintain records of any risk analysis performed," and
>
> (2) Section 4.4.8 states "[a]s part of design validation, the supplier shall perform and maintain records of clinical evaluations . . . Clinical evaluation may include a compilation of relevant scientific literature, historical evidence that similar designs and/or materials are clinically safe . . . ."

Ex. Q, ISO 13485:1996 at 4.

The very title of the 2003 version of ISO 13485 – "Medical Devices – Quality Management Systems – Requirements for regulatory purposes" – makes clear that this standard is yet another European regulatory standard. Ex. T, ISO 13485:2003. In addition, Ms. Wilson concedes that the FDA has not adopted ISO 13485 and that medical device manufacturers in the United States are not required to comply with ISO 13485. Ex. E, Wilson 9/17/15 Dep. Tr. 180:17-180:21; Ex. K, Duncan 10/6/15 Dep. Tr. 334:4-334:9.

D. EN 1441 – the first EU regulation focused on risk analysis was not adopted until 1998

The very first "standard" Ms. Wilson cites for her opinions that is specifically devoted to risk analysis is EN 1441. Ex. U, EN 1441. EN 1441 is the first standard that called for a risk analysis to be performed during the design phase of medical device development. *Id*. at 3. This standard was adopted as a European regulatory standard. *Id*. at 1. Ms. Wilson acknowledges that this standard was not implemented until April 1998, not only after TVT had been fully designed, but also after TVT had been cleared for market in the U.S. Ex. F, Wilson 3/22/16 Dep. Tr. 13:5-14:17; Ex. S, Wilson Deposition Exhibit 11 at 3. EN 1441does not contain any provision calling for retroactive application to devices that had already been designed. Moreover, EN 1441 does not address modern day requirements for ongoing risk assessments and risk management that are the subjects of Ms. Wilson's reports, other than one terse statement that "[i]n the light of new data a review of the risk analysis will be required." Ex. U, EN 1441 at 6.

E. ISO 14971 was first adopted as an EU regulation in 2000

Next, MS. Wilson cites ISO 14971 as "the primary standard in the medical device industry defining how to perform risk management, and remains the guiding standard today." Ex. B, TVT Report at 6; Ex. V, ISO 14971:2000; Ex. W, ISO 14971:2007. In her TVT report,

Ms. Wilson improperly relies heavily on post-2000 ISO 14971 standards for her criticisms of a product designed prior to 1995. E.g., Ex. B, TVT Report at 6-10, 15 (setting forth the framework for the remainder of her report analysis). There is nothing in ISO 14971 that required retroactive application. In fact, ISO 14971 expressly recognizes that is impossible. Ex. W, ISO 14971:2007 at 41 ("It is recognized that the manufacturer might not be able to follow all the processes identified in this International Standard . . . such as . . medical devices designed prior to the publication [of] this International Standard.").

Finally, let there be no mistake – ISO 14971 is yet another standard developed for regulatory purposes. *Id*. at 15. The FDA has recognized ISO 14971:2007 as a consensus standard, but the FDA has also issued many guidance documents that further refine the guidance for proper for risk management. Thus, it is impossible for Ms. Wilson to fully and properly evaluate Ethicon's compliance with ISO 14971:2007 without engaging in her normal practice of reviewing and relying upon FDA guidance documents, which she chose not to do here.

F. The use of EU regulatory standards is unfairly prejudicial

The only "industry standards" in the United States are the FDA regulations and guidance documents. This Court has previously ruled that FDA regulatory standards and Ethicon's compliance therewith are inadmissible, and Ethicon here does not seek to revisit the issue. Ethicon submits, however, that any probative value that comes from Ethicon's alleged failure to comply with inapplicable European regulatory standards is unfairly prejudicial in the light of the Court's prohibition on evidence of Ethicon's compliance with the applicable United States regulatory standards. Fed. R. Evid. 403.

Even if the Court were otherwise inclined to permit opinion testimony that relies on compliance with ISO 13485, it is not possible to evaluate such compliance accurately without

referencing FDA regulations. That is because ISO 13485 effectively incorporates FDA regulations by virtue of its numerous direct references to compliance with regional regulations as part of compliance with this ISO standard. Ex. T, ISO 13485:2003 at Sections 1.2, 3, 3.3, 3.6, 3.8, 4.2.1 f), 4.2.3, 4.2.4, 5.5.1, 5.5.2, 5.6.2, 6.1b), 6.2.2, 7.2.1c), 7.3.2b), 8.1, 8.2.1, 8.3 and 8.5.1. Similarly, one cannot fully evaluate Ethicon's compliance with ISO 14971 without reference to FDA standards. This is because the risk/benefit analysis, a key component of risk management under this ISO, requires the use of "local laws" to determine whether a risk is acceptable. Ex. W, ISO 14971:2007 at 16. Thus, if the jury is not permitted to hear testimony concerning compliance with FDA regulations, then Ethicon would be unfairly prejudiced by the exclusion of critical testimony concerning compliance with ISO 13485 and 14971.

Moreover, again, none of the regulations on which Ms. Wilson relies says that it is retroactive. It does not make sense to say that regulations governing documentation of a process should be applied retroactively. In fact, in response to public comment questions 1996, the FDA specifically declared that the new Quality Management Systems standards which the United States put into place in late 1997 did not require retrospective creation of design control documentation. Medical Devices, Current Good Manufacturing Practice (CGMFP) Final Rule, Quality System Regulation, 61 Fed. Reg. 52,602, 52,616 (Oct. 7, 1995).

Ms. Wilson's testimony is not reliable because she is improperly attempting to impose post-1997 standards retrospectively to when TVT was designed in Sweden in the early 1990s. *See, e.g.*, Ex. B, TVT Report at 13-15. Moreover, she improperly fails to consider the regulatory standards the FDA imposes on certain risk monitoring activities today, *see* 21 C.F.R. Part 820 ("Quality Systems"). Instead she addresses post-1997 European regulatory standards but, in order to circumvent this Court's rulings about regulatory evidence, she calls them "industry

standards." Ex. K, Duncan 10/6/15 Dep. Tr. 331:23-334:9; *see also* Ex. X, Council Directive 93/42/EEC (these are the European regulations, akin to the FDA's quality systems regulations, that did not become mandatory until 1998; standards such as EN 46001, EN 1441, ISO 13485 and ISO 14971, discussed above, were adopted by the European regulatory authorities pursuant to these regulations). There are in fact no such "industry standards" apart from the regulatory framework.

The mental and logical gyrations necessary to outline this brief explanation of what she is doing are reason enough to exclude her testimony, because there is little chance that any of this could be made comprehensible to a lay jury. In addition, because Ms. Wilson applies the wrong legal standard, while pretending not to follow any legal standard at all but "industry" standards, her opinions are legally irrelevant and should be excluded. Moreover, all of Ms. Wilson's opinions concerning design controls and design risk analysis for TVT should be excluded for the additional reason that the standards on which she relies do not apply retroactively.

III. Ms. Wilson's Opinions Are Not Reliable Because She Did Not Consider All of the Documents Available

Ms. Wilson's ultimate opinion is that there is an absence of evidence. *See, e.g.*, Ex. B, TVT Report at 3, 13, 15, 21. She claims to have reviewed "all" of the relevant documents and concluded that Ethicon's design control process and risk management were deficient because she finds no document of certain events transpiring. Ms. Wilson's opinions are flawed because she did not review all of the facts and data available.

First, Ms. Wilson only looked at the documents that Plaintiffs' counsel gave her, and she assumed – incorrectly – that no other documents existed. Second, from her already incomplete set of documents, Ms. Wilson consciously excluded from consideration relevant documents that address the very processes and analyses that she claims are missing from Ethicon's files.

To be admissible, expert testimony must be based upon "sufficient facts or data" Fed. R. Evid. 702. Ms. Wilson's opinions do not satisfy the reliability requirements of Rule 702 and *Daubert*. Accordingly, her proposed opinion testimony should be excluded in its entirety.

A. Ms. Wilson's opinions are based on incomplete records cherry-picked by Plaintiffs' counsel

Ms. Wilson admits that her opinions are based only on the documents "that [she] saw." Ex. E, Wilson 9/17/15 Dep. Tr. 46:2-46:8; *see also id.* at 35:17-36:2 (stating that her reliance list contains all documents "that [she] had available to [her]"). Importantly, Ms. Wilson did not conduct an independent review of the documents produced in this litigation. Instead, she relied upon counsel for Plaintiffs to select the documents that she reviewed.

> A. I asked for anything related to risk management or risk analysis. Anything on the topic whatsoever.
>
> Q. And are you comfortable that you have all those documents?
>
> A. I am not a hundred percent sure. . . .

Id. at 68:14-68:20.

Concrete examples of the incompleteness of Ms. Wilson's review, include:

- As discussed below, she failed to review a number of critical risk assessment documents. This omission is critical because her opinion that Ethicon failed to properly conduct risk management during the ongoing life of the TVT device ignores the very documents that evidence the ongoing risk management.
- She reviewed none of the clinical literature for TVT. *Id*. at 426:9-426:17. This omission is critical because she relies on ISO 14971:2007 which expressly states that a medical device is defined as "state of the art" when it has become "generally accepted" as demonstrated in the clinical literature. Ex. W, ISO 14971:2007 at 39-40.
- She failed to review the pre-clinical testing and design assessment. Ex. E, Wilson 9/17/15 Dep. Tr. 383:15-384:18.
- She reviewed none of the position statements of expert users, i.e. surgeons, regarding TVT. *Id*. at 221:8-223:9. Again, this omission is critical because ISO 14971:2007 states that a medical device is defined to be "state of the art" when it has become

"generally accepted as good practice." Ex. W, ISO 14971:2007 at 39; *see also* Ex. Y, AUGS Position Statement.

- She reviewed none of the audits related to TVT. Ex. E, Wilson 9/17/15 Dep. Tr. 122:22-123:13, 293:21-295:17. This omission is critical because the auditors were examining for compliance to the applicable standards for design controls and risk management, the very matters on which she opines.

Moreover, Ms. Wilson consciously disregarded all documents related to design control process audits because the scope of her assignment was artificially limited *to exclude* "regulatory submissions or anything like that." *Id.* at 123:1-123:3. By her own admission, the regulatory audits would have a file accompanying the final audit report, which would contain checklists regarding the documents reviewed and processes followed by the auditor. *Id.* at 122:17-122:21.

Not only did she ignore the regulatory submissions, but she made no effort to obtain the documentation that supported the regulatory submissions. *Id.* at 123:7-123:13.

B. Ms. Wilson erroneously limited her analysis to Ethicon's FMEAs and thus failed to consider critical documents

Ms. Wilson acknowledges that the EN and ISO standards do not require any specific format or technique for risk analysis. Ex. B, TVT Report at 8. However, her reports ignore this acknowledgement by critiquing Ethicon's risk analyses and ongoing risk management during the lifecycle of its products solely from the perspective of whether Ethicon performed and continually updated dFMEAs throughout the lifecycle of the products. *See generally* Ex. B, TVT Report; Ex. C, TVT-O Report; Ex. D, TVT-S Report. In particular, her principal criticism of Ethicon's post-market risk management of TVT, TVT-O, and TVT-S is that Ethicon did not treat the FMEA as a "living document," which she expressly explains to mean that in her view whenever Ethicon received new data it should have updated its FMEAs. Ex. B, TVT Report at 10. This is a fundamental flaw that pervades the entirety of Ms. Wilson's reports.

Contrary to Ms. Wilson's focus solely on an FMEA technique for risk analysis, EN 1441 lists an FMEA as but one possible technique for risk analysis and specifically provides that "[t]he need for, selection of and use of such techniques . . . is outside the scope of this standard." Ex. U, EN 1441 at 6. Ms. Wilson's reports do not cite any standard requiring the use of an FMEA technique.

Like EN 1441, ISO 14971 discusses several risk analysis techniques, including an FMEA, but nowhere requires any specific technique or format. Ex. V, ISO 14971:2000 at 18, 26-27, 35-36; Ex. W, ISO 14971:2007 at 9, 56-59, 76-77. The techniques discussed in ISO 14971 vary depending on such matters as whether the analysis is conducted in the design phase, whether the analysis relates to toxicological hazards or biocompatibility, whether the analysis relates to a change in an existing product, whether the analysis is part of a design benefit/risk assessment, and whether the analysis is that of post-market data and post-market benefit/risk assessment. Ex. W, ISO 14971:2007 at 9, 12-14, 19, 43-44, 56-59, 76-77. However, Ms. Wilson's reports evaluate Ethicon's risk management for TVT, TVT-O, and TVT-S ***solely*** in the context of her views of what a design failure modes and effects analysis ("dFMEA") should entail. *See generally* Ex. B, TVT Report; Ex. C, TVT-O Report; Ex. D, TVT-S Report. The result is that Ms. Wilson expresses many opinions that Ethicon failed to consider matters that she thinks are important, when in fact the matters are addressed in risk management documents that she did not consider and did not address in her reports.

C. Ms. Wilson ignored Ethicon's biocompatibility risk assessments

With respect to potential biological hazards such as Ms. Wilson's discussion of degradation in all three of her reports, she completely ignored the fact that ISO 14971 directs the reader to ISO 10993 for the techniques for risk analysis of biocompatibility, including degradation. Ex. V, ISO 14971:2000 at 18, 26-27; Ex. W, ISO 14971:2007 at 9, 76-77; Ex. F,

Wilson 3/22/16 Dep. Tr. 76:8-76:22. Ms. Wilson acknowledged that she is not an expert in the application of ISO 10993. Ex. F, Wilson 3/22/16 Dep. Tr. 73:23-74:23. ISO 10993 states the standards for biocompatibility risk assessments, including the subject of degradation. *See generally* Ex. Z, ISO 10993-1:1997; Ex. AA, ISO 10993-9:1999; Ex. BB, ISO 10993-13:1998. Ethicon has performed multiple biocompatibility risk assessments for its Prolene mesh pursuant to ISO 10993, and thus addressed degradation. *See, e.g.*, Ex. CC, 1995 Prolene Mesh Risk Analysis and Biocompatibility Risk Analysis; Ex. DD, 1997 Prolene Mesh Risk Analysis, Biocompatibility Risk Analysis and Literature Review; Ex. EE, 2000 TVT Biocompatibility Risk Assessment. However, because these risk assessments were performed pursuant to FDA Program Memorandum #G95 and ISO 10993 instead of Ms. Wilson's concept of an FMEA, she ignored these critical risk assessments.[3] Even if she had reviewed them, she admits that she is not qualified as an expert on ISO 10993. Ex. F, Wilson 3/22/16 Dep. Tr. 73:23-74:23. Ms. Wilson's opinions regarding degradation should be excluded for these reasons alone.

Additionally, Medscand performed clinical studies that demonstrated the safety and efficacy of TVT. Ex. FF, *An Ambulatory Surgical Procedure Under Locsl Anesthesia for Treatment of Female Urinary Incontinence*, Int Urogynecol J (1996) 7:81-86; Ex. GG, *A Multicenter Study of Tension-Free Vaginal Tape (TVT) for Surgical Treatment of Stress Urinary Incontinence*, Int Urogynecol J (1998) 9:210-213; Ex. HH, *A three year follow up of tension free vaginal tape for surgical treatment of female stress urinary incontinence*, British Journal of Obstetrics and Gynecology, April 1999, Vol. 106, pp. 345-350. Ethicon also performed substantial clinical evaluations of the TVT mesh material, not to mention the many years of

[3] Another problem the Court should consider is that if Ms. Wilson is permitted to testify concerning degradation, then Ethicon will be unfairly prejudiced because Ethicon's biocompatibility risk assessments state on their face that they are designed to comply with the FDA's Program Memorandum #G95 requirements for analysis of biocompatibility, which includes chemical degradation, whereas the Court has already determined that evidence concerning compliance with FDA standards must be excluded.

historical evidence of clinical use of the TVT mesh material dating back to the 1970s. Ex. CC, 1995 Prolene Mesh Risk Analysis and Biocompatibility Risk Analysis; Ex. DD, 1997 Prolene Mesh Risk Analysis, Biocompatibility Risk Analysis and Literature Review. However, there is no mention of any of these risk analyses and historical evidence anywhere in Ms. Wilson's reports. Ms. Wilson simply failed to consider these important analyses.

D. Because Ms. Wilson ignored the ISO 14971 mandate to rely on prior risk analyses of similar devices, she did not review the incorporated risk analyses

1. Ethicon's 1995 and 1997 Prolene mesh risk analyses

Ms. Wilson's criticisms of Ethicon's risk analyses of TVT, TVT-O, and TVT-S are directed to the Prolene mesh component which is the same in all three devices and has been marketed for many years for similar uses in the human body. Even though not required to do so, Ethicon prepared risk analyses for its Prolene mesh in 1995 and again in 1997. Ex. CC, 1995 Prolene Mesh Risk Analysis and Biocompatibility Risk Analysis; Ex. DD, 1997 Prolene Mesh Risk Analysis, Biocompatibility Risk Analysis and Literature Review. Ms. Wilson did not consider these risk analyses. Ex. F, Wilson 3/22/16 Dep. Tr. 67:5-73:12.

In contrast, ISO 14971 provides that when a risk analysis has already been performed for a similar device, "it can and should be applied to save time, effort and other resources." Ex. W, ISO 14971:2007 at 19. Considering that Ms. Wilson was focused solely on FMEAs, these risk analyses take on even more importance because in an FMEA performed in accordance with ISO 14971, "[c]omponents are analysed one at a time, thus generally looking at a single-fault condition." *Id*. at 57. In contrast, Ms. Wilson's concept of an FMEA is the opposite of that stated in ISO 14971. Ex. F, Wilson 3/22/16 Dep. Tr. 48:24-49:3 ("Q. Okay. And would you agree that an FMEA is a technique by which you look at the effect of individual components systematically? A. You look at -- no"). Ms. Wilson opines that the "scope" of an FMEA is

required to be " 'the medical device' rather than components." Ex. C, TVT-O Report at 12. Contrary to ISO 14971, Ms. Wilson says that an FMEA must be on a "system level," not an individual component level. *Id.*; *see also* Ex. F, Wilson 3/22/16 Dep. Tr. 39:24-43:18.

2. Ethicon's TVT-O risk analysis

TVT-O is the exact same medical device as TVT, except that the mesh is implanted in the body via a different route and thus uses different delivery instruments. *See generally* Ex. II, TVT-O Clinical Expert Report. The mesh itself is implanted in the same location in the body as TVT and performs the same as TVT once implanted. *Id*. Ms. Wilson's principal criticism of Ethicon's TVT-O risk analysis is that the analysis did not re-analyze the Prolene mesh component, but instead relied on Ethicon's prior risk analyses on the Prolene mesh component of TVT. Ex. C, TVT-O Report at 12. She used the exact same flawed reasoning as that stated in subsection a., above. Her opinions concerning the risk analysis for TVT-O should be excluded because she is not applying the ISO 14971 mandate to rely on prior risk analysis on components that have already undergone risk analysis.

3. Ethicon's risk/benefit analyses, complaint reviews and clinical expert reports

Ethicon's internal procedure PR602-003 provides for different types of risk analyses, particular as related to post-marketing risk management. Ex. JJ, PR602-003 Version 17 (this procedure has undergone a number of revisions over the years as standards have changed). These include complaint reviews, risk/benefit analyses, preparation of hazards/harms tables using post-marketing data, literature reviews, clinical expert reports and clinical evaluation reports. Over the years Ethicon has employed a number of these various analyses, including analyses that address the various specific risks that Ms. Wilson opines were ignored. Ex. KK, 2000 Clinical Expert Analysis Of Reported Risks; Ex. LL, 2001 Risk Analysis; Ex. MM, 2001 Complaint Review; Ex.

NN, 2001 Clinical Expert Analysis Of Reported Risks; Ex. OO, 2006 Complaint Review; Ex. PP, 2008 Complaint Review; Ex. QQ, 2010 Complaint Review; Ex. RR, 2010 Clinical Evaluation Report; Ex. SS, 2013 Clinical Evaluation Report.

Ms. Wilson discusses risks that she says Ethicon did not properly evaluate. Ex. B, TVT Report at 20-21, 24-31. To the extent these are hazards or harms that have ever been reported, they in fact were evaluated in several of Ethicon's risk analyses. Exs. KK, LL, MM, NN. Some of these risks were no longer reported at all by 2006, but those that still had any occurrence were included within the 2006-2013 analyses listed above. Exs. OO, PP, QQ, RR, SS. Only one of these analyses, the 2001 Risk Analysis (Ex. LL), was considered in Ms. Wilson's reports (Ex. LL is discussed separately below). Ms. Wilson did not consider the remainder of these analyses because they did not fit into her strict concept of a risk analysis being only in the format of an FMEA. Ex. F, Wilson 3/22/16 Dep. Tr. 61:9-61:22, 65:24-66:5, 66:9-67:4.

Contrary to Ms. Wilson's view, ISO 14971 specifically encourages the use of risk/benefit analyses, literature reviews, clinical reports, and expert opinion as means for identifying, estimating and evaluating risks. Ex. W, ISO 14971:2007 at 9, 12, 39-40, 43-45. In fact, ISO 14971 mandates that a manufacturer establish a system to identify and evaluate potential risks that are reported post-production. *Id*. at 13-14. There is absolutely no requirement anywhere in ISO 14971 that the information be fed back into a pre-market FMEA.

In her deposition, Ms. Wilson revealed another reason she did not consider Ethicon's various risk analyses listed above. Ms. Wilson admits that she is not qualified to evaluate clinical expert reports, clinical evaluation reports and risk/benefit analyses. Ex. F, Wilson 3/22/16 Dep. Tr. 28:8-28:21, 52:23-53:10. Her lack of qualification is further shown by her testimony that clinical evaluation reports (CER) are not even part of the risk management process. *Id*. at 30:10-

30:15, 49:22-50:6. CERs are an extremely important part of the risk management process. Ethicon's procedure for risk management specifically emphasizes the key role of a CER in the risk management process. Ex. JJ, PR602-003 at 14-16.

The Court should not permit Ms. Wilson to testify to opinions concerning Ethicon's risk management system for TVT, TVT-O, and TVT-S when she has not considered, and admits that she is not qualified to consider, the most critical documents that address the very deficiencies that she alleges exist.

IV. Ms. Wilson's Opinions Are Not Reliable Because She Misapplied the European Regulatory Standards

A. Ms. Wilson applies the wrong standard for acceptability of risks

ISO 14971 specifically defines "safety" as "freedom from unacceptable risk." Ex. W, ISO 14971:2007 at 4. However, in evaluating TVT, TVT-O, and TVT-S, Ms. Wilson applies a standard that ISO 14971 states is impossible for any medical device to meet:

> Q. Okay. Would you agree that it's beyond the scope of your three reports for you to attempt to opine that any of the risks associated with TVTR, TVTO, or TVTS are unacceptable?
>
> . . . .
>
> A. No. I believe it is stated in my report that these risks are unacceptable because they are in the field, causing harm.

Ex. F, Wilson 3/22/16 Dep. Tr. 58:16-59:8. ISO 14971 defines safety in the manner stated above because it recognizes "that 'absolute safety' in medical devices [is] not achievable." Ex. W, ISO 14971:2007 at 15. If Ms. Wilson's view of safety was the standard, then there would be no reason for ISO 14971 to mandate the use of risk/benefit analyses. Ms. Wilson's opinions should be excluded because she is applying the wrong standard by which to evaluate risk management of TVT, TVT-O and TVT-S.

B. Ms. Wilson misapplies "state of the art' under ISO 14971

An important consideration of risk management is to understand the "state of the art" in connection with the design and development of a medical device. ISO 14971 explains that "state of the art" means "what is currently and generally accepted as good practice" for a medical "solution" to a health problem. Ex. W, ISO 14971:2007 at 39-40. However, Ms. Wilson's opinions are based solely on her view of the state of the art for performing "risk management," not the state of the art for the medical solution at issue. Ex. F, Wilson 3/22/16 Dep. Tr. 52:8-53:3. Thus, her opinions ignore a key factor in risk/benefit determinations. Ms. Wilson's opinions condemning TVT, TVT-O, and TVT-S should be excluded because she fails to conduct a proper analysis under ISO 14971.

C. Ms. Wilson misapplied EN 46001 retroactively to Medscand's quality records

As noted, Medscand was not required to comply with the standards on which Ms. Wilson relies. Nevertheless, as part of the licensing of TVT in 1996-1997, Ethicon required that Medscand comply with EN 46001 (and ISO 9001 to the extent referenced in EN 46001). Ms. Wilson criticizes Medscand's compliance because not all of Medscand's compliance documents are available today. Ex. B, TVT Report at 15. There was no standard in place that required Medscand to retrospectively prepare and maintain quality control records on a device designed prior to 1995. Ms. Wilson does not cite any authority for her implied proposition that Medscand was required to maintain its compliance documents and have them available for her review more than 17 years after it sold the TVT product to Ethicon. Nevertheless, there is proof of Medscand's compliance shown in Ethicon's own audits of Medscand in the 1990s and shown by the European Notified Body audits that Medscand obtained. *See*, *e.g.*, Ex. G, EC Certificate DGM-036; Ex. H, Certificate TÜV Q1Z 00 07 39858 001; Ex. I, TÜV Audit Brief Report Order

no. 70038068; Ex. J, TÜV Audit Brief Report Order no. 70063863; *see also* Ex. E, Wilson 9/17/15 Dep. Tr. 109:19-110:5, 112:17-113:2, 115:7-115:23.

Ms. Wilson criticizes these audits (which criticism Ethicon hotly disputes). Ex. B, TVT Report at 14. However, the bottom line is that the industry standards on which Ms. Wilson relies simply did not apply retroactively to Medscand's design of TVT. Moreover, Ms. Wilson concedes (1) that she has no information to support her speculative criticism of the audits and (2) that to obtain a specific European regulatory mark – the CE mark – a full audit had to have been performed. Ex. E, Wilson 9/17/15 Dep. Tr. 175:22-176:11.

D. Ms. Wilson failed to fully evaluate Ethicon's compliance with ISO 13485

Perhaps most troubling in light of this Court's previous rulings concerning the FDA is the fact that it is impossible for Ms. Wilson to fully and properly evaluate Ethicon's compliance with ISO 13485 without examining and discussing Ethicon's compliance with FDA requirements. That is because ISO 13485 is replete with numerous direct references to compliance with regional regulations as part of compliance with this ISO standard. Ex. T, ISO 13485:2003 at Sections 1.2, 3, 3.3, 3.6, 3.8, 4.2.1 f), 4.2.3, 4.2.4, 5.5.1, 5.5.2, 5.6.2, 6.1b), 6.2.2, 7.2.1c), 7.3.2b), 8.1, 8.2.1, 8.3 and 8.5.1.

E. Ms. Wilson's criticism of the "TVT-R MCM Design History File" is unsupported

Ms. Wilson severely criticizes Ethicon's Design History File for TVT. Ex. B, TVT Report at 15. However, she ignores that Ethicon did not purchase TVT until 1999 and thus for obvious reasons would not have pre-market "design requirements documents, design review or design verification records or dFMEA" for a device designed by a different manufacturer more than four years earlier at a time when this documentation was not required.

F. Ms. Wilson's discussion of "Design History File Remediation"

Ms. Wilson purports to quote an Ethicon document stating "Ethicon Germany as the designated design control location undertook DHF remediation by generating missing documents, to both fulfill requirements and prevent future problems related to change control." Ex. B, TVT Report at 15 (purporting to quote from ETH.MESH.22136776, Ex. TT). Ms. Wilson significantly misquoted the document in order to create a false impression. Moreover, she opines that the falsely quoted statement was concerning TVT when in fact it concerned only a needle attachment change that was underway when Ethicon purchased TVT from Medscand. Even though TVT was exempt from the new pre-market design controls in EN 46001, those design controls do apply to any ***changes*** made to a pre-existing product. Since a change was being made to the needle attachment, Ethicon was simply complying with EN 46001 limited to the scope of the needle change. This memo had nothing to do with the overall TVT device.

Next, Ms. Wilson deceitfully associates the document discussed in the preceding paragraph with Ethicon's creation of design controls and a dFMEA for the TVT device in 2001, discussed below. Ex. B, TVT Report at 16. It is true that Ethicon created retrospective design controls and dFMEA for the TVT device in 2001, but instead of "generating missing documents, to both fulfill requirements" as Ms. Wilson opines, the 1,418-page file in which these documents appear plainly show that this work was done as part of yet another change -- this time the change affected the entire device because Ethicon was adding blue colorant to the previously clear mesh material. In 2001 the FDA's quality systems regulations in the U.S. and EN 46001 and EN 1441 in Europe were applicable to this new change. This, for the first time, required that Ethicon prepare design controls for the overall device as part of the design change.

G. Ms. Wilson applies the wrong standards in her analysis of Ethicon's 2001 dFMEA

Ms. Wilson is severely critical of Ethicon's 2001 dFMEA prepared in anticipation of the change to add blue colorant to TVT. Ex. B, TVT Report at 16-18; Ex. LL, 2001 dFMEA. First, she says it is "too late." Ex. F, Wilson 3/22/16 Dep. Tr. 105:3-106:2. Ms. Wilson opines that "[i]f the hazards are not properly identified and prioritized in the design phase, they cannot be mitigated through a change to the design of the system or by adding protective measures in the device or labeling." Ex. B, TVT Report at 15. This opinion effectively condemns every device placed on the market prior to the adoption of risk analysis standards. This opinion also suggests that post-market risk management is too late. This is a gross misapplication of ISO 14971. ISO 14971 was developed for the very purpose of providing for the "manage[ment of] risks from medical devices throughout their life-cycle" in order to keep a watchful eye for previously unrecognized hazards and harms so that new risks can be managed if necessary. Ex. W, ISO 14971:2007 at 15. ISO 14971 expressly recognizes that products developed before the standard became effective will not have a previous risk analysis. *Id.* at 41. "In this case, the manufacturer should take special account of the need for additional risk control measures." *Id.* That is precisely what Ethicon did as discussed in Section III.C.4., above, but as discussed above Ms. Wilson ignored these risk control measures simply because they were not in the form of a dFMEA.

Next, Ms. Wilson applies Ethicon's internal operating standards PR602-003, OP650-010 and OP650-011 to judge the 2001 dFMEA. Ex. B, TVT Report at 11-13; Ex. F, Wilson 3/22/16 Dep. Tr. 108:4-108:10. Ms. Wilson just assumes that these were the applicable procedures. *Id.* at 108:11-111:24. However, the 2001 dFMEA does not bear any resemblance to these procedures and thus would obviously appear not to be credible if indeed those were the correct procedures to

apply. This led Ms. Wilson to opine that the 2001 dFMEA is "not credible." Ex. B, TVT Report at 16. Ms. Wilson knew that the 2001 dFMEA was performed in Germany, but made no effort to locate the correct procedure by which to evaluate the 2001 dFMEA. Ex. F, Wilson 3/22/16 Dep. Tr. 109:1-118:8. She now acknowledges that she has never seen the correct operating procedure by which to evaluate the 2001 dFMEA. *Id.*; Ex. UU, Procedure QSV 4-02 Version 7. At her deposition, Ms. Wilson scoffed at this procedure saying it was written in German. Ex. F, Wilson 3/22/16 Dep. Tr. 115:17-118:5. Indeed, the first eight pages are in German, but the next twelve pages show both the German and English translations and the last eight pages are the English version of the first eight pages. Ex. UU, Procedure QSV 4-02 Version 7. Either Ms. Wilson was not provided this correct procedure or she chose not to try to understand it. In either event, her opinions concerning the 2001 dFMEA are not reliable due to her failure to apply the correct procedures.

V. Ms. Wilson Is Unqualified To Offer Certain Opinions

A. Ms. Wilson is unqualified to opine regarding medical assessments

Ms. Wilson operates in the area of regulatory compliance, and she is not a medical doctor. Ex. E, Wilson 9/17/15 Dep. Tr. 129:21-129:22. When she consults in a non-litigation capacity, Ms. Wilson is not the person on the regulatory compliance team who would provide expertise regarding medical issues. *Id.* at 140:23-141:2. She admits that she is not qualified to opine regarding anything to do with implantation or physicians (*id.* at 134:4-134:10) and that she is not qualified to perform a medical assessment (*id.* at 159:14-159:23). Furthermore, she did not review the medical literature nor the position statements that support the use of TVT. *Id.* at 126:11-126:21.

In her work experience, she has never consulted with a medical device company on mesh devices (*id.* at 24:19-24:21), devices to treat stress urinary incontinence (*id.* at 25:24-26:4), or

devices used to treat any pelvic floor disorder (*id.* at 26:5-26:8). She has never performed a failure mode effects analysis for a stress urinary incontinence device. *Id.* at 146:17-146:20. She has never performed a device design safety assessment for a stress urinary incontinence product or a pelvic floor product. *Id.* at 146:21-147:8.

Despite this dearth of education and experience, Ms. Wilson's report is replete with medical opinions. Specifically, throughout her report, she attempts to opine regarding whether certain characteristics of TVT present a risk to humans. *See generally, e.g.*, Ex. B, TVT Report at 24-31. These opinions are beyond the scope of her qualifications and should be excluded.

B. Ms. Wilson is unqualified to opine regarding IFU warnings

At the conclusion of her reports, Ms. Wilson includes a paragraph critiquing the TVT, TVT-O and TVT-S IFUs. Specifically, e.g., she claims that Ethicon failed to update the "TVT Device's Warning Information." *See, e.g.*, Ex. B, TVT Report at 32. Again, Ms. Wilson is not a physician. Her credentials indicate no experience drafting an IFU or product warnings. Simply put, Ms. Wilson lacks any and all expertise in the area of IFUs and product warnings, and, therefore, should be precluded from offering any opinion testimony regarding same.

CONCLUSION

For all of these reasons, Ms. Wilson's opinions are irrelevant, unreliable, and should be excluded from the trial of this matter.

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **WAVE THREE TVT, TVT-O AND TVT-S CASES LISTED ON EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that I have this day electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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